

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

In the Matter of)	
)	
Rules and Regulations Implementing the)	CG Docket No. 02-278
Telephone Consumer Protection Act of 1991)	

To the Commission:

COMMENTS OF SILVERLINK COMMUNICATIONS, INC.

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SUMMARY

Silverlink Communications, Inc. (“Silverlink”), is a leading provider of automated, interactive voice solutions for the healthcare industry. Silverlink urges the Federal Communications Commission (“Commission”) to exempt health-related telephone calls that are exempted and permitted under the Federal Trade Commission’s (“FTC”) automated telemarketing rules from the Commission’s automated telemarketing rules because such health-related automated calls are entirely distinguishable from telemarketing calls, are already subject to extensive regulation under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)¹, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”)², and provide valuable public health information to consumers.

Individually tailored health-related automated calls subject to HIPAA range from a simple administrative interaction (to confirm an address, for example) to a sophisticated clinical interaction (a disease-specific health risk assessment, for example). Unlike other automated calls, health-related automated calls subject to HIPAA do not contain advertisements and are delivered to support consumer health. The Department of Health and Human Services and the FTC have both carefully weighed the benefits of health-related automated calls against consumer privacy concerns and determined that health-related automated calls are important. As a safety measure to prevent abuse, HIPAA contains a strict regulatory regime for health-related automated calls to ensure that consumer privacy and health information is protected.

An express exemption from the Commission’s telemarketing rules for health-related automated calls subject to HIPAA is in the public interest because health-related automated calls are already subject to a highly regulated regime under HIPAA, the FTC adopted an exemption for health-related automated calls subject to HIPAA, the calls provide important public health information to consumers, the calls are unlike telemarketing calls that are a nuisance to consumers, and the calls are to telephone numbers provided by the beneficiary expressly for receiving health information.

¹ Pub. L. No. 104-191, 110 Stat. 1936 (1996) (*codified, as amended, at 42 U.S.C. §§1320 et seq.*).

² The HITECH Act, Title XIII of the American Recovery and Reinvestment Act, Pub. L. No. 111-5, §13000 et seq., 123 Stat. 115, 226-279 (2009) (“HITECH Act”).

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Silverlink Communications, Inc. (“Silverlink” or “Company”), acting with counsel and pursuant to Section 1.415(b) of the Federal Communications Commission’s (“FCC” or “Commission”) Rules, 47 C.F.R. § 1.415(b), hereby respectfully submits comments on the Commission’s Notice of Proposed Rule Making, released in CG Docket No. 02-278 on January 22, 2010, concerning the harmonization of the FCC’s prerecorded telemarketing call rules under the Telephone Consumer Protection Act (“TCPA”) with those recently revised by the Federal Trade Commission (“FTC”) pursuant to the Telemarketing Sales Rule (“TSR”).³

I. INTRODUCTION

Silverlink urges the Commission to exempt health-related telephone calls that are exempted and permitted under the FTC’s automated telemarketing rules from the FCC’s

³ *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, Notice of Proposed Rule Making*, 25 FCC Rcd 1501 (2010) (“NPRM”). Silverlink’s comments are timely filed in accordance with the schedule established in the NPRM and as published in the Federal Register. 75 Fed. Reg. 13471 (Mar. 22, 2010).

automated telemarketing rules because such health-related automated calls are entirely distinguishable from telemarketing calls, are already subject to extensive regulation under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)⁴, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”)⁵, and provide valuable public health information to consumers.⁶

In the *NPRM*, the FCC seeks comment on whether it should adopt an exemption to its automated call rules consistent with the exemption adopted by the FTC for health-related automated calls, what authority it has under the TCPA to adopt such an exemption, and how to reconcile the HIPAA written notice requirements for marketing purposes with such an exemption.⁷

As explained below, the Department of Health and Human Services (“HHS”) has been authorized by Congress to balance the competing public interests relating to health communications and health information privacy.⁸ Silverlink strongly encourages the FCC to

⁴ Pub. L. No. 104-191, 110 Stat. 1936 (1996) (*codified, as amended, at 42 U.S.C. §§1320 et seq.*).

⁵ The HITECH Act, Title XIII of the American Recovery and Reinvestment Act, Pub. L. No. 111-5, §13000 et seq., 123 Stat. 115, 226-279 (2009).

⁶ See Exhibit A, Automated Call Consumer Survey. This same survey was provided to the FTC. The survey results indicate that consumers find automated health-related automated calls subject to HIPAA to be more helpful than typical automated calls; consumers are more willing to listen to automated health-related automated calls subject to HIPAA than to typical automated calls; for a variety of reasons unrelated to privacy, some consumers may not understand the benefits of opting in to receive automated health-related automated calls subject to HIPAA and will not take the steps necessary to receive such calls even though they find the calls helpful; and consumers generally do not like automated calls but have a more positive opinion of automated health-related automated calls subject to HIPAA.

⁷ *NPRM*, ¶¶ 34-35.

⁸ Congress, the FTC, HHS and the FCC have established parallel, complementary privacy regimes. The regimes do not undercut each other and are designed to safeguard privacy in different realms, i.e. commercial, health, etc. For health privacy issues, it is important for the FCC to consider the comprehensive regulatory scheme established and enforced by HHS. Any rules adopted by the FCC should not disrupt HHS’ carefully crafted privacy regime for health information.

adopt a policy identical to the FTC's policy, and defer to the existing regulatory regime surrounding health-related automated calls pursuant to HIPAA rules and regulations.

A. Health-Related Automated Calls Subject to HIPAA are Exempted and Permitted Under the FTC's Rules Because Such Calls are Already Regulated Under HIPAA and Provide Important Public Health Information To Consumers.

After compiling and reviewing an extensive record, the FTC identified the following six reasons for adopting an exception from its automated call rules for healthcare-related automated calls:

- “[F]irst among them [is] the fact that delivery of healthcare-related prerecorded calls subject to HIPAA already is regulated extensively at the federal level.
- Second, coverage of such calls by the amendment could frustrate the Congressional intent embodied in HIPAA, as well as other federal statutes governing healthcare-related programs.
- Third, the number of healthcare organizations who might call a patient is inherently quite limited—as is the scope of the resulting potential privacy infringement—in sharp contrast to the virtually limitless number of businesses conducting commercial telemarketing campaigns.
- Fourth, there is no incentive, and no likely medical basis, for healthcare organizations who place healthcare-related prerecorded calls to attempt to boost sales through an ever-increasing frequency or volume of calls.
- Fifth, the existing record does not persuade the [FTC] that it should find that ‘the reasonable consumer’ would consider prerecorded healthcare calls coercive or abusive.
- Sixth, FTC law enforcement experience does not suggest that healthcare-related calls have been the focus of the type of privacy abuses the amendment is intended to remedy.”⁹

In reaching its decision to exempt health-related automated calls subject to HIPAA from its automated call rules, the FTC concluded that the application of its rules to health-related

⁹ *Telemarketing Sales Rule*, 73 Fed. Reg. 51164, 51192 (Aug. 29, 2008).

automated calls “is not necessary to prevent the unfair or deceptive act or practice[s that harm consumers] to which the [the FTC’s TSR] relates.”¹⁰

We respectfully submit that the FCC should follow the FTC’s lead and adopt a similar exemption from its automated call rules for health-related automated calls subject to HIPAA. Such an exemption is necessary because health calls are already regulated on the federal level, such calls benefit consumers by providing public health information, health calls are not the type of nuisance calls that the TCPA was designed to stop, and health calls promote the public interest by proving a needed service to consumers.

B. Silverlink is a Premier Provider of Health-Related Automated Calls Subject to HIPAA

Silverlink is a leading provider of automated, interactive voice solutions for the healthcare industry.¹¹ Its services enable health enterprises, including health plans, pharmacy benefit managers (“PBMs”), specialty pharmacies, and disease management/population health companies to deliver personalized, interactive, and HIPAA-compliant phone messages to millions of healthcare consumers - including elderly and chronically ill consumers who rely upon such messages for their health care needs.

Silverlink’s prerecorded (though interactive), privacy-protected messages delivered to individual healthcare consumers have been highly successful in driving positive health outcomes

¹⁰ *Id.*

¹¹ Silverlink is one of a limited number of companies that offer voice response solutions exclusively for the healthcare industry. An exception to the FCC’s automated call rules for health-related automated calls subject to HIPAA would only apply to the limited number of companies that offer voice response solutions for healthcare industry, not just Silverlink. The FTC felt comfortable that such an exemption could be carefully crafted to avoid abuse because HIPAA provides a regulatory regime that defines who is HIPAA regulated or a “covered entity”/“business associate”, and only these narrowly-defined companies are authorized to make automated health-related automated calls without a consumer’s prior written consent.

and generally lowering healthcare costs. These types of calls made by Silverlink, as well as by other entities such as PBMs, health plans, and other HIPAA-regulated entities, include but are not limited to: health screening reminders including mammogram reminders and colonoscopy reminders, prescription drug refill reminders, availability of cost savings options such as brand to generic drug conversions, flu shot reminders, child immunization reminders, medical equipment reorders for Medicare populations with chronic diseases, benefit plan selection reminders, and disease management plan reminders.

Silverlink clients determine when they would like to execute a call program, what they would like to say, and exactly which members they would like to communicate with. Based on the urgency of the communication, they may attempt to reach the call recipient up to four times, with an average of only two attempts. Further, Silverlink's call program policies are designed to ensure efficiency for its clients and a positive call experience for the individual. For example, should a call recipient confirm his or her identity and decide to hang-up before a call is completed, no further attempts would be made during that call program to reach that individual. If no answer is achieved during an attempt, a brief voicemail message with an inbound toll-free number and PIN may be left for the recipient so that he or she may call back and retrieve the recorded message later, at his or her convenience.

Silverlink collaborates with clients to ensure that consumers are not inundated with automated health-related automated calls subject to HIPAA, but rather, are contacted efficiently and effectively in order to minimize the number of calls received. In addition, if Silverlink or similarly situated companies are not sensitive to consumer needs then the consumer may request that the company discontinue placing calls – and such requests are always honored.

C. Health-Related Automated Calls Subject to HIPAA Enable Effective, Efficient and Essential Communications between Healthcare Organizations and Consumers

In the last 8 years, Silverlink, for example, has worked with 80 of the largest and most influential healthcare enterprises in the country to inform healthcare customers of health-related information using prerecorded calls. Individually tailored health-related automated calls subject to HIPAA are not one-way “blast” messages or “robocalls” that the TCPA was designed to address. Call types range from a simple administrative interaction (to confirm an address, for example) to a sophisticated clinical interaction (a disease-specific health risk assessment, for example). Recipients are also able to provide information during the call. Recipients can respond and navigate through the call using their voice rather than having to enter numbers on the phone key pad. Each call is customized, and can be personalized based on the recipient’s needs, language, cognitive ability, type of treatment and insurance coverage. Such calls provide a natural experience, often allowing a recipient to repeat information or to transfer to a live agent.

Healthcare covered entities use automated calls to reach consumers at home to educate, encourage proactive healthcare decisions, and collect information across a wide variety of healthcare contexts. More detailed descriptions of prominent types of automated health-related automated calls subject to HIPAA are provided below:

- **Flu shot and other immunization reminders:** Automated calls are used to reach consumers directly to encourage recommended immunizations, such as routine immunizations for children and flu shots for seniors. Automated reminder calls demonstrably improve immunization rates.

Each winter, the flu kills approximately 36,000-40,000 Americans, hospitalizes more than 200,000, and costs the U.S. economy over \$10 billion in lost productivity and direct medical expenses. [Source: Trust for America’s Health, 2006]

- **Refill reminder / reorder calls:** Using automated calls, mail order pharmacies contact patients at the appropriate time in their refill cycle to complete a refill order, ensuring that

the patient has an uninterrupted supply of his or her medication. Consumers become accustomed to receiving these monthly or quarterly refill calls and benefit from them. Studies show that, in the absence of such refill reminders, up to 70% of patients with long-term prescriptions fall off therapy. Noncompliance with drug regimens can have significant adverse impact, and increase hospitalization, morbidity and mortality rates. For example, failure of a patient with newly diagnosed hypertension to comply with a prescribed course of medication may cause heart attack, stroke or sudden death. Similar to refill reminders, automated calls are used to inform members when one or more of their medical supplies (such as diabetes test strips) is running out and provide the option to reorder.

[Medication non-compliance] is estimated to result in 125,000 deaths due to cardiovascular disease (such as heart attack and stroke) each year. In addition, up to 23% of nursing home admissions, 10% of hospital admissions, and many doctor visits, diagnostic tests, and unnecessary treatments could be avoided if people took their drugs as directed. [Source: The Merck Manual Home Edition for Patients and Caregivers. "Compliance with Drug Treatment." Available at www.merck.com]

- **Availability of cost savings opportunities to migrate from branded to generic drugs:** Automated calls are used to inform consumers of prescription availability in a generic form and the benefits of a change from brand forms. Successful migrations reduce co-payments by the patient and costs to the insurer or healthcare plan provider.

The FDA notes that generic drugs typically cost 50-70 percent less than their brand-name counterparts [Source: <http://www.fda.gov/>]

Americans could save \$24.7 billion this year if they were prescribed more generics in six major drug classes for treating conditions such as heart disease, ulcers, pain, depression, high blood pressure and high cholesterol. [Source: 2005 Generic Drug Usage Report, Express Scripts, Inc.]

- **Health screening reminders:** When consumers reach appropriate ages or are diagnosed with specific diseases or conditions, automated calls are used to encourage screenings such as mammograms, colonoscopies and blood glucose level checks. These preventative screenings yield tremendous benefit for consumers.

Only 49 percent of adults received preventive and screening tests according to guidelines for their age and sex. [Source: U.S. Healthcare System Gets Poor Scores on Quality, Access, Efficiency and Equity, The Commonwealth Fund dated Sept. 27, 2006]

Estimated 37,000-81,000 avoidable deaths in the United States due to variations in care in 2005. Estimated \$2.9 billion - \$3.9 billion in avoidable medical costs due to variations in care in 2005. Estimated \$10.6 billion in lost productivity due to suboptimal care among U.S. workforce in 2005. [Source: National Committee for Quality Assurance, The State of Health Care Quality Industry Trends and Analysis 2006]

- **Enrollment encouragement:** Automated calls are used to improve health outcomes and beneficiary access to benefits, such as enrolling in disease management or preventative care programs. Newly eligible Medicare and Medicaid beneficiaries might receive an automated call encouraging them to take advantage of their eligibility and the availability of low income subsidies to help pay for prescription drugs. Medicaid beneficiaries may receive a call letting them know that they are eligible for Medicare. This addresses a major challenge in healthcare cost management, ensuring patients are enrolled in insurance plans and care management programs. Automated calls may also be used to notify beneficiaries of the availability of generic prescription drugs and to see if a beneficiary needs assistance with their post-hospital care.
- **Retail to mail migration encouragement:** Automated calls are used to encourage patients with maintenance medication requirements to use mail order pharmacies rather than traditional retail outlets. Often patients are not aware of their mail order benefits, so these calls raise awareness, improve convenience, and lower costs for both patients and healthcare fiduciaries.

All Silverlink calls involving protected healthcare information comply with HIPAA's privacy rules.

D. Health-Related Automated Calls Subject to HIPAA Regulation are Cost Effective and an Efficient Method for Communicating Important Public Health Information to Consumers.

Cost-effective healthcare decision support calls to individuals lead to improved health outcomes and cost savings. Automated healthcare calls provide the most cost-effective means of communication, and surveys indicate that consumers appreciate such calls and want to continue receiving them. Healthcare organizations using automated calls to reach consumers at home, consistently achieve success rates dramatically higher than those for mail, email or web portals. Automated calls reduce costs and increase effective consumer contact at a fraction of the cost of live calls. Using automated calls is becoming a public health necessity, particularly because staff limitations often preclude making live calls to large numbers of patients.

The following alternatives to automated calls are significantly less effective and/or more costly for healthcare fiduciaries:

- **Email** - With response rates in the low single digits, email is ineffective. Additional hurdles include lack of current email addresses, inability to comply with HIPAA rules covering protected health information, and limited access to senior citizens. Most consumers know that important health-related messages could be easily lost due to the amount of mail received in a single day. Important health-related messages could also be confused with junk mail and inadvertently deleted.
- **Traditional mail** - With typical response rates ranging in the single digits and teens, traditional mail is slightly more effective than email, but requires interaction through sending paper forms to a recipient, who must then complete and return them by mail, a process that can take weeks or longer, and therefore is still not nearly as effective as automated or live phone calls. Mail is also more costly, less efficient and less effective than automated calls.
- **Web portals** – Most healthcare fiduciaries have made significant investments in sophisticated websites in recent years. Though these sites have the potential to become effective communication vehicles, current consumer adoption rates remain in the single digits. Because they require the customer to initiate contact, they suffer from the very problem they seek to address through proactive outreach, namely, patient inertia.
- **Live calls** - Live phone calls, which can cost \$6 to \$20 each, can be effective and desirable, but are usually cost prohibitive as a means to communication with a large number of individuals. Many call centers also have turnover rates approaching 75% per year, which present training challenges and make it difficult for healthcare organizations to achieve consistently accurate messaging through live calls.

Overall, automated healthcare calls subject to HIPAA deliver the best value to healthcare fiduciaries and patients, as indicated by the following sample of published case studies and testimonials:

Automated Speech-Enabled Program Description	Outcomes	Source
Diabetic screening reminder	Diabetic retinal exams increase from 71% to 93% due to the outreach program.	<i>Highlights of GAO-04-022 a report to the Minority, Member, Committee on Health, Education, Labor, and Pensions, U.S. Senate</i> Benefits Realized for Selected Health Care Functions, Appendix 1, Use of Information Technology for Selected Health Care Functions (p. 107)
Adolescent vaccination	Rate of adolescents	<i>Highlights of GAO-04-022 a</i>

Automated Speech-Enabled Program Description	Outcomes	Source
reminder	receiving full schedule of vaccinations increased from 29% to 43% due to the outreach programs.	<i>report to the Minority, Member, Committee on Health, Education, Labor, and Pensions, U.S. Senate</i> Benefits Realized for Selected Health Care Functions, Appendix 1, Use of Information Technology for Selected Health Care Functions (p. 107)
National childhood immunization outreach	Project Vaccinate demonstrated an increase from 57.7% to 72.5% in immunizations rates for the 4:3:1:3:3 (4 DTap, 3 IPV, 1 MCV, 3 Hip, 3 Hep B) in 19-35 month-olds in Newark over the course of one year – a 26% increase.	Blue Cross Blue Shield Association
Flu shot reminder program	65% of consumers reached by interactive automated call actually obtained a full shot.	Proprietary data
Member engagement in cardiovascular disease program	69% of members reported weight loss during the program. Meanwhile, the average LDL reduced from 127.7 mg/dL to 87.4 mg/dL during participation in the program.	MAMSI Health Plans, 2002

- “In 18 months [our use of prerecorded calls] has saved members \$11 million, says Beth Bierbower, Humana’s vice president of product innovation.” (U.S. News and World Report online edition Oct. 29, 2006)
http://www.usnews.com/usnews/health/articles/061029/6plan_4.htm
- “According to Rees Pinney, senior vice president of sales and marketing for Familymeds, the automated system ... received high marks from customers.” (EWeek Oct. 7, 2004)
<http://www.eweek.com/article2/0%2C1759%2CI668068%2COO.asp>
- “Within a week we were finished scripting the calls ... [we] found that 70% of [our] members listened to the automated message ... The lower than expected number of

customer service calls-showed that most members were comfortable with interactive phone calls ... The interactive calls have saved us time because they resulted in less disruption in our customer service center. .. However, the whole focus was to increase member satisfaction. By giving members the information they need to manage their drugs, we were able to do that.” Ellen Scharaga Director of Pharmacy, EmblemHealth (Health Data Management Feb. 2005)

- “This innovative way of having a voice-activated, consumer-friendly call [allows us] to reach out to more of our customers in a more timely fashion,” [Noreen] Patterson [Vice President of Marketing and Advertising, FamilyMeds] said. The company had used workers at individual pharmacies to do the task, a practice that was time consuming and expensive.” (Mass High Tech Dec. 15, 2005)

As the published cases and testimonials indicate, health-related automated calls subject to HIPAA produce positive health outcomes that reduce healthcare expenses, hospitalizations and deaths.

1. Health-Related Automated Calls Subject to HIPAA Have a Positive Impact on Consumers

Data show that consumers appreciate and want to receive automated healthcare calls. Trends in managed care are making consumers increasingly responsible for managing and funding their own healthcare. As consumers are required to accept more choice, responsibility and risk, they need and want better access to the information necessary to make the best decisions for themselves and their families. Automated calls enable healthcare fiduciaries to effectively and affordably deliver personalized information when it is most relevant to the recipient.

When consumers receive automated calls from their healthcare fiduciaries, they overwhelmingly respond positively and are willing to engage with the caller. Interaction rates for automated healthcare calls, meaning the percentage of recipients who answer the call and respond to the first question without hanging up, typically exceeds 75%. Interaction rates for other calls are much lower, 17% for financial services and 2% interaction rate for utility services.

Below are further examples of consumer acceptance of automated healthcare calls:

- Of 140,000 consumers receiving an automated call from their pharmacy benefit manager with a refill/reorder offer, only 50 opted out of future calls.
- A covered entity reported that after sending automated interactive calls to 60,000 Medicaid members, only 10 asked not to be contacted again.
- On average, 20% of consumers who receive, by automated call, a message from their healthcare company left on an answering machine or with a household member place a return call.¹²

In some cases, healthcare fiduciaries use automated healthcare calls subject to HIPAA to reach the nation's most vulnerable populations, who might otherwise not be served. Interacting with persons eligible for Medicaid or other public benefits requires a cost-effective approach with a broad reach. Automated calls are often the only way to reach this population in a cost effective manner. For example, healthcare fiduciaries successfully used automated calls to contact tens of millions of Medicare Part D members, collecting and delivering information with speed and efficiency that would not be possible with any other method. Automated health-related automated calls subject to HIPAA also offer healthcare fiduciaries and cost effective way to reach the elderly and the sick, who may have limited access to other modes of communications.

2. Consumers Rarely Opt-Out of Receiving Future Health-Related Automated Calls Subject to HIPAA

Silverlink conducted an informal survey of its clients to determine how often consumers opt-out of receiving automated health related calls subject to HIPAA. The survey indicates that only a small percentage of consumers opt-out of such calls, and the survey also confirms that the

¹² Silverlink believes that the healthcare benefits far outweigh any perceived cost resulting from leaving messages on answering machines. The messages left are brief and do not disclose protected health information. In addition, HIPAA's privacy rule permits healthcare providers to leave messages for patients on their answering machines. See <http://www.hhs.gov/ocr/hipaa> (Frequently Asked Questions).

existing HIPAA regulatory regime clearly enables consumers to opt-out when they want to – without the need for further regulatory restrictions.

Silverlink has identified three different types of opt-out processes currently employed by healthcare organizations during prerecorded messages: (1) interactive opt-out; (2) hybrid interactive/1-800 opt-out; and (3) 1-800 opt-out. The data below are based on a relatively small sampling of actual client program. Opt-out results for the various processes are outlined below (results vary depending upon the call program type).¹³

- Interactive Opt-Out - allows call recipient to electronically opt-out of future calls realtime:
 - Percentage of Total Contacted Recipients Electing Opt-Out: 5-12% Estimate
- Hybrid Interactive/1-800 Opt-Out - allows call recipient to stop the recorded call immediately if they elect to opt-out and provides the recipient with a toll-free number to call and complete the opt-out:
 - Percentage of Total Contacted Recipients Electing Opt-Out: 3-5% Estimate
- 1-800 Opt-Out - provides the recipient with a toll-free number to call and complete the opt-out:
 - Percentage of Total Contacted Recipients Electing Opt-Out: 1-3% Estimate

¹³ The opt-out results provided below are based on limited data. Only a small number of Silverlink's clients currently use the interactive opt-out and hybrid interactive/1-800 opt-out methods. The interactive opt-out percentage was derived from two sources - the opt-out call data of one Silverlink client and the experience of another industry member; the interactive opt-out rates vary from 5 to 12 percent due to variations in call type, age of the target audience, and other factors. The hybrid interactive/1-800 opt-out percentage was derived from the call opt-out data of one Silverlink client on one call program. Finally, the 1-800 opt-out data were based on feedback with a sampling of Silverlink clients since Silverlink does not have any direct data on 1-800 opt-outs (call recipients directly contact one of Silverlink's clients to opt-out). While the data provided are based on the experience of a limited number of clients, and are estimates, Silverlink believes these results are representative of the opt-out rates for the types of calls placed by Silverlink and other healthcare organizations.

These low opt-out rates suggest that consumers view health-related automated calls subject to HIPAA differently from telemarketing calls, appreciate the receipt of such calls, and value the public health information provided during the calls. Health-related automated calls subject to HIPAA contain an 800 number for consumers to call with questions or to opt-out of receiving future calls.

In the *NPRM*, the Commission seeks comment on if it should likewise adopt an exemption from any automatic opt-out requirement for health-related automated calls subject to HIPAA.¹⁴ The FTC adopted a full exemption from its telemarketing rules, including its opt-out requirements, for health-related automated calls subject to HIPAA after a thorough review to ensure that consumers would continue to be able to receive important health information from health organizations and health providers.¹⁵ The Commission should adopt a similar exemption since health-related automated calls subject to HIPAA are extensively regulated by HIPAA and to ensure that consumers continue to receive important health information.

3. The Unique Nature of Health-Related Automated Calls Subject to HIPAA Precludes Abusive Calls.

Unlike telemarketing calls, health-related automated calls subject to HIPAA provide public health information directly related to the consumers' medical history. The unique nature of HIPAA-regulated health-related automated calls, which are placed on behalf of health care enterprises such as health plans, PBMs, specialty pharmacies, and disease management

¹⁴ *NPRM*, ¶ 42.

¹⁵ 73 Fed. Reg. at 51191 (“The Commission has given careful consideration to the possibility of exempting healthcare calls from the express written agreement requirement of the amendment, while requiring that they comply with its opt-out provisions. The difficulty with such a partial exemption in the healthcare context, as some of the commenters argue, is that a partial exemption may create a health or safety risk. ... For this reason, the Commission is persuaded that a complete exemption from the amendment for healthcare related calls is necessary.”).

companies, discourages prerecorded telemarketing campaigns that consumers would find abusive such as the placement of repeat calls to the same individuals to obtain repeat sales. The relationship among Silverlink, the healthcare entity, the employer, and healthcare consumers is complex and multi-faceted. Accordingly, unlike traditional telemarketing, it is in the commercial self-interest of the call sponsor to ensure that it does not alienate its clients' members. This unique relationship results in a communication control mechanism and an environment of self-regulation. Not surprisingly, therefore, Silverlink works with its clients to ensure that members do not experience call fatigue or become alienated due to repeat calls. If Silverlink is not sensitive to consumer needs and their willingness to receive automated health calls regulated by HIPAA, then Silverlink will be forced out of business because consumers will no longer be willing to receive such calls.

E. Healthcare Reform will Increase the Need for Health-Related Automated Calls Subject to HIPAA.

The implementation of healthcare reform¹⁶ will require extensive regulatory action over several years, and across at least three administrative agencies (HHS, IRS, and NAIC); healthcare providers and organizations will need to cost effectively communicate with their beneficiaries about changes to their healthcare coverage. A key goal of healthcare reform is to control the rising costs of healthcare. Health-related automated calls subject to HIPAA will permit healthcare organizations to effectively and affordably communicate important health information and to audit calls made to beneficiaries.

¹⁶ The Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148 (2009) and the Health Care and Education Reconciliation Act ("HCERA"), Pub. L. 111-152, 124 Stat. 1029 (2009).

It is anticipated that the implementation of healthcare reform will dwarf the Medicare Part D¹⁷ implementation in terms of complexity and scale, during which CMS released multiple regulations and clarifying memoranda. Based on Silverlink's experience with Medicare Part D implementation, the volume of regulations and the corresponding tight deadlines will result in increased usage of health-related automated calls subject to HIPAA by healthcare organizations to communicate with consumers. Silverlink's customers used health-related automated calls subject to HIPAA, for example, to inform consumers about Medicare Part D, and also for required administrative functions (e.g., Annual Notice of Change, Coordination of Benefits).

Healthcare reform will affect the majority of the U.S. population and in particular, an estimated thirty million new enrollees, and will provide for a strict enforcement regimen. For example, healthcare reform requires insurers to achieve new medical loss ratios ("MLR"), or rebate their members for the difference at the end of each plan year. MLRs measure the ratio of premium revenue spent on profits and administrative costs to that spent on reimbursements for healthcare and other healthcare activities. The new MLRs – effective in 2011 – require insurers to spend 80% of premium revenue for individual and small group plans on medical costs; and 85% of premium revenue for group plans on medical costs.¹⁸ Several U.S. Senators have expressed their interest in closely monitoring how this provision is implemented, to ensure that insurers are not manipulating the system. In this environment, health insurers will be looking for effective, efficient, and cost-saving options to hold down administrative costs without compromising the quality of care. Health-related automated calls subject to HIPAA provide

¹⁷ Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066 (2003).

¹⁸ PPACA, Pub. L. No. 111-148 § 10101.

health insurers with an efficient, cost effective and auditable means of communicating health-related information to their members.

II. THE TCPA WAS CREATED TO STOP UNWANTED TELEMARKETING CALLS, NOT HEALTH RELATED CALLS SUBJECT TO HIPAA.

With the increased use of automated dialers in the early 1990s, the FCC, FTC, state regulatory agencies, local telephone companies and congressional offices started to receive a significant number of complaints about unwanted telemarketing calls.¹⁹ Consumers were frustrated because they did not have a way to stop the unwanted calls. Congress has addressed these concerns by giving the FTC, the FCC and HHS the ability to regulate unwanted telemarketing calls.²⁰

A. The Creation of the TCPA Focused on Giving Consumers a Way to Stop Unwanted Telemarketing Calls, Not Valuable Health-Related Automated Calls Subject to HIPAA.

In response to consumer complaints that telemarketing and automated calls were a nuisance, an invasion of privacy, and an impediment to interstate commerce, Congress passed the TCPA.²¹ Consumers identified the following problems with telemarketing calls:

- automated calls are placed to lines reserved for emergency purposes, such as hospitals and fire and police stations;
- the entity placing the automated call does not identify itself;

¹⁹ Senate Report, 102-718, 1st Sess., 102nd Cong. (1991), *reprinted in* 1991 U.S.C.A.N. 1968, 1969.

²⁰ Do-Not-Call Implementation Act, Pub. L. No. 108-20, 117 Stat. 557 (2003), *codified at* 15 U.S.C. § 6101; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996), *codified, as amended, at* 42 U.S.C. § 1320 *et seq.*; Telemarketing and Consumer Fraud and Abuse Prevention Act of 1994, Pub. L. No. 103-297, 108 Stat. 1545 (1994), *codified at* 15 U.S.C. § 6101 *et seq.*; Telephone Consumer Protection Act of 1991, Pub. L. No. 102-243, 105 Stat. 2394 (1991), *codified at* 47 U.S.C. § 201 *et seq.*

²¹ S. Rep. 102-178 at 1969.

- the automated calls fill the entire tape of an answering machine, preventing other callers from leaving messages;
- the automated calls will not disconnect the line for a long time after the called party hangs up the phone, thereby preventing the called party from placing his or her own calls;
- automated calls do not respond to human voice commands to disconnect the phone, especially in times of emergency;
- some automatic dialers will dial numbers in sequence, thereby tying up all the lines of a business and preventing any outgoing calls; and
- unsolicited calls placed to fax machines, and cellular or paging telephone numbers often impose a cost on the called party (fax messages require the called party to pay for the paper used, cellular users must pay for each incoming call, and paging customers must pay to return the call to the person who originated the call).²²

By way of comparison, health-related automated calls provide important public health information to consumers and HIPAA strictly regulates the content of health-related automated calls and the companies that may deliver such calls. HIPAA health-related call restrictions were developed specifically to address consumer complaints about automated telemarketing calls.

The TCPA restricts telemarketing calls to residential lines and prescribes how and under what circumstances a telemarketer may call a residence.²³ Congress explained that the TCPA does not apply to calls “where the called party has in essence requested the contact by providing the caller with their telephone number for use in normal business communications.”²⁴ Therefore, under the TCPA, health-related automated calls subject to HIPAA made to a number provided by a consumer as part of an application for health insurance or in order to receive medical care are permissible business communications because the number was provided by the consumer to the healthcare provider for contacting the consumer regarding health issues.

²² *Id.*

²³ 47 U.S.C. §227 *et seq.*

²⁴ H. Rep., 102-317, 1st Sess., 102nd Cong. (1991) at 13.

Consistent telemarketing restrictions between the FCC and the FTC have concerned Congress. When the Do Not Call Implementation Act was passed, Congress directed the FCC to adopt TCPA final rules that maximize consistency with those of the FTC.²⁵ After the FTC amended its Do Not Call rules, the FCC conducted a proceeding to do the same.²⁶ During the FCC's Do Not Call proceeding, the FCC concluded that establishment of a single Do Not Call list was in the public interest and consistent with the mandate from Congress. The FCC entered into a Memorandum of Understanding with the FTC to ensure that a single Do Not Call list and the FCC's and FTC's rules would be harmonized. The FCC should adopt an express exemption from its rules for automated health-related automated calls subject to HIPAA to ensure that the FCC's actions do not interfere with the regulatory regime established under HIPAA and the FTC's rules.²⁷

B. Health-Related Automated Calls Subject to HIPAA Regulation are Permissible Under the TCPA.

Under the FCC's rules, health providers may deliver health-related automated calls subject to HIPAA because the calls are not commercial in nature, there is an existing business relationship between the caller and the called party, the number was provided by the consumer to

²⁵ Pub. L. No. 108-10, 117 Stat. 557 (2003), *codified at* 15 U.S.C. § 6101.

²⁶ *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, Report and Order*, 18 FCC Rcd 14014 (2003).

²⁷ If the FCC decides not to adopt an express exemption from its rules for automated health-related automated calls subject to HIPAA, it should forbear from enforcing its automated call rules for such calls. This will make clear that health-related automated calls subject to HIPAA made to a consumer's telephone number provided to a healthcare profession, like calls to a debtor on a phone number provided in a debt application, do not violate the FCC's rules. See *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991 and Request of ACA International for Clarification and Declaratory Ruling, Declaratory Ruling*, 23 FCC Rcd 559, ¶ 9 (2008) ("ACA") (stating calls to a debtor on a telephone number provided by the debtor in a debt application do not violate the FCC's rules).

the provider for use in the normal course of business, or the consumer provided prior express consent to receive health-related automated calls subject to HIPAA.²⁸

1. Section 227(b)(2)(B)(i) of the FCC’s Rules Permit Commercial Automated Calls Not Made for a Commercial Purpose, Such as Health-Related Automated Calls Subject to HIPAA.

Section 227(b)(2)(B)(i) of the Communications Act of 1934, as amended, (the “Act”), permit automated calls that are not made for a commercial purpose.²⁹ The FCC defines a “telephone solicitation” as a telephone call or text message for purposes of encouraging the purchase or rental of goods and services.³⁰ Health-related automated calls subject to HIPAA, unlike telemarketing calls, are specifically tailored for the consumer and provide important public health information.

The relationship among healthcare organizations, an employer, and a healthcare consumer are complex and entirely distinguishable from the relationship between a consumer and typical telemarketer. Specifically, unlike typical telemarketing calls:

- The healthcare relationship involves highly beneficial and protected health-related information;
- The entities placing the calls are subject to HIPAA’s Privacy Rule and marketing limitations;³¹

²⁸ However, an express exemption for health-related automated calls subject to HIPAA would clarify that the FCC’s prior inaction regarding such calls does not mean that they are prohibited under the FCC’s rules. It would also make the FCC’s automated call rules consistent with the FTC’s automated call rules for health-related automated calls subject to HIPAA and preserve the health privacy regime developed by HIPAA for health-related automated calls.

²⁹ 47 U.S.C. § 227(b)(2)(B)(i).

³⁰ 47 C.F.R. § (f)(ii)(12) (“The term *telephone solicitation* means the initiation of a telephone call or message for the purpose of encouraging the purchase or rental of, or investment in, property, goods, or services, which is transmitted to an person”)

³¹ The HHS’ Office of Civil Rights is responsible for HIPAA privacy rule enforcement. Since April 2003, “HHS has received over 50,989 HIPAA Privacy complaints. We have resolved over eighty-nine percent

- In many cases, the calls relate to services already prescribed by health care practitioners;
- In many cases, the calls require a new prescription by a health care practitioner in order for the consumer to obtain the applicable service or product identified in the call;
- In most cases, a third-party payer is involved in the transaction - either the government, employer, or managed care entity; and
- In all cases the consumer receiving the call has a preexisting health-related relationship with the entity on whose behalf the call is placed.

Accordingly, unlike traditional telemarketing, it is in the commercial self-interest of the call sponsor to ensure that it does not alienate the called party. The above-mentioned complex relationship infrastructure creates an environment of self-regulation, and discourages prerecorded telemarketing campaigns that consumers would find abusive. These factors are evident in the low opt-out data for HIPAA-regulated calls.

The FCC concluded that product recall calls and the offer to schedule an appointment for any necessary related repairs, are not telephone solicitations.³² “We clarify that telephone calls to residential subscribers for the limited purpose of informing consumers of recalls due to a product safety or defect concern and scheduling appoints to correct such problem at no cost to the consumer are not prohibited under the Commission’s [rules]” provided that a telephone

of complaints received (over 45,493); through investigation and enforcement (over 10,515); through investigation and no violation (5,462); and through closure of cases that were not eligible for enforcement (29,496).” *Enforcement Highlights*, Department of Health and Human Services, as of Mar. 31, 2010, available at <http://www.hhs.gov/ocr/privacy/hipaa/enforcement/highlights/index.html>. The FTC also aggressively enforces the TSR by collecting consumer complaints and then investigating offending companies. Those investigations have resulted in nearly two hundred court orders and millions of dollars in fines since 2002. See *Telemarketing Fraud and Abuse Enforcement Action Announcements Since October 1, 2002*, Federal Trade Commission, available at <http://www.ftc.gov/bcp/cases/telemarkfraudenforcement/index.shtml> and *FTC Testifies on the “Call Center Consumer’s Right to Know Act,”* Federal Trade Commission, dated Sept. 11, 2008, available at <http://www.ftc.gov/opa/2008/09/callcenter.shtm>.

³² *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991 and National Automobile Dealers Association Petition for Declaratory Ruling, Declaratory Ruling*, 20 FCC Rcd 10736, ¶¶ 4-5 (2005) (“NADA”) and ACA, ¶ 9 (stating calls to a debtor on a telephone number provided by the debtor in a debt application do not violate the FCC’s rules).

solicitation is not initiated.³³ The FCC argued that “this clarification will ensure that consumers are made aware of potential safety concerns involving products that they have purchased and have an opportunity to correct those defects in a timely manner.”³⁴ Likewise health-related automated calls subject to HIPAA provide consumers with access to health information to ensure that consumers are receiving the follow up care they need after surgery and continue to take their medications as prescribed. Also, there is no indication that the FTC’s exception for health-related automated calls subject to HIPAA from its telemarketing rules has resulted in a loophole. So far, the exception as narrowly tailored to prevent abuse, has worked well and a similar exemption should also work well at the FCC.

2. Section 227 (b)(2)(B)(ii) Permits Commercial Calls that Do Not Adversely Affect the Privacy Rights of the Called Party and that Do Not Transmit an Unsolicited Advertisement.

Section 227(b)(2)(B)(ii) of the Act, allows automated commercial calls that do not interfere with consumer privacy rights and do not contain advertisements.³⁵ Health-related automated calls subject to HIPAA provide consumers with specifically tailored public health information to meet their needs. Unlike other automated calls, health-related automated calls subject to HIPAA do not contain advertisements and are delivered to support consumer health. The people in most need of reminders (i.e. the ill and the elderly) are the least likely to sign up for such reminders. Privacy rights are protected under HIPAA and apply to automated healthcare calls. HIPAA restricts the content of health-related automated calls and who may deliver those calls. As discussed in greater detail below, HHS and the FTC have both carefully weighed the benefits of health-related automated calls against consumer privacy concerns and determined that

³³ NADA, ¶ 5.

³⁴ *Id.*, ¶ 6.

³⁵ 47 U.S.C. § 227(b)(2)(B)(ii).

health-related automated calls were important. HIPAA contains a strict regulatory regime for health-related automated calls to ensure that consumer privacy and health information is protected.

Health-related automated calls subject to HIPAA are more similar to permitted recall calls than traditional telemarketing calls that are trying to sell goods and/or services. In *NADA*, the FCC determined that recall telephone calls that are not coupled with the sale of goods and services are permitted under the FCC's rules because they are delivering important information to consumers.³⁶ Similar to the safety information provided during permitted recall calls, health-related automated calls subject to HIPAA provide important public health information to consumers and do not contain advertisements. More specifically, the TCPA was not designed to prohibit calls to a number provided by a consumer during the normal course of business.³⁷ Consumers provide health professionals a telephone number on which they want to be contacted about health-related information.

III. HIPAA PRIVACY RULES APPROPRIATELY RESTRICT ACCESS TO CONSUMER INFORMATION IN ORDER TO ENSURE THAT CONSUMERS DO NOT RECEIVE HARASSING TELEMARKETING CALLS.

The HIPAA privacy rules were carefully considered and weigh consumer privacy rights and the need to provide consumers with beneficial public health information. Health-related automated calls subject to HIPAA are valued by consumers and are expressly permitted by the comprehensive regulatory regime established under HIPAA.

³⁶ *NADA*, ¶¶ 4-6.

³⁷ H. Rep. at 13.

A. The HIPAA Marketing Rules Fully Regulate Not Only the Entity that May Place Health-Related Automated Calls to Consumers but the Information that May Be Communicated During Such Calls.

Based on feedback from interested parties, HHS concluded that the public interest in unfettered communications for healthcare purposes outweighed the intrusion on privacy interests, and its final HIPAA privacy rules exempted healthcare communications from any patient authorization requirement. Healthcare providers and their fiduciaries may call patients about health-related issues such as surgery follow-up, health plans and provide reminders for prescriptions and appointments. For example, Silverlink's services are provided pursuant to a specific written contract with health professionals so Silverlink only has access to patient information as a business associate fiduciary of the covered entity. The Company urges the FCC to defer to HHS's public policy determination and to adopt the same policy decision adopted by the FTC by exempting automated healthcare calls subject to HIPAA from its proposed rules.

1. The HIPAA Privacy Rules.

In promulgating the HIPAA privacy rules regulating communications that encourage consumers to purchase or use products or services, the HHS exempted communications:

- (i) To describe a health-related product or service . . . that is provided by, or included in a plan of benefits of, the covered entity making the communications . . . ; (ii) For treatment of the individual; or (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.³⁸

Thus, healthcare fiduciaries do not need prior authorization to communication with consumers about their health plan benefits, treatment, case management, care coordination or healthcare alternatives, and the healthcare sector has relied on this exemption in developing its practices, procedures and policies for the use of communication technology. The use of automated health-

³⁸ 45 C.F.R. § 164.501.

related automated calls subject to HIPAA will be critically important for delivering cost effective messages to consumers during healthcare reform enactment. Health-related automated calls subject to HIPAA are a highly cost effective way for healthcare organizations to provide important information to consumers.

To show just how sophisticated the HHS has been in its drafting and re-drafting of the Privacy rule to account for and affirmatively prevent these types of abuses (i.e., random calls from pharmacies, other providers), it is necessary to look at the history of the HIPAA Privacy Rule. Under the December 2000 proposed Privacy Rule, later modified in 2002, the proposed Privacy Rule required a covered entity to obtain an individual's authorization to use or disclose protected health information ("PHI") for purposes of marketing. In other words, if a communication did not fall within one of the exceptions to the marketing definition under the Privacy Rule, and the communication fell under the definition of "marketing," the Privacy Rule's provisions restricting the use or disclosure of PHI for marketing purposes would have applied.³⁹ For these marketing communications, the individual's authorization was required before a covered entity could use or disclose PHI because there is no relationship between the caller and the called party.

Thus, the HHS initially, and unintentionally, prohibited all marketing communications in the proposed December, 2000 Privacy Rule without an authorization, but given the overwhelming backlash from the healthcare industry, and HHS' realization that such a prohibition would significantly impede the quality of and access to healthcare, HHS decided to affirmatively allow treatment communications and certain healthcare operations activities

³⁹ See 45 C.F.R. § 164.508(a)(3)(i) (stating that "a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing ...").

without obtaining and authorization from the individual. The Privacy Rule was, thereby, eventually and specifically modified to exclude and intentionally allow unimpeded communications about patient treatment and certain healthcare operations activities through a revised definition of “marketing.” Such communications and activities may include, for example, automated calls for health screening reminders (including mammogram reminders and colonoscopy reminders), prescription drug refill reminders, brand to generic drug conversions, flu shot reminders, child immunization reminders, managed care enrollment calls, and retail-to-mail pharmacy conversions. Such services are included in most standard plans of care across the nation. In most cases, most of the cost is borne by the health plan and not the consumer, and may often reduce consumer expense (e.g., by utilizing lower cost generic drugs, or preventing expensive hospitalization for noncompliant patients) and improve quality of care. Covered entities and their business associates may engage in such “marketing”-exempt communications without first obtaining patient authorization.

An additional reference of note is the simple citation to the Privacy Rules and Section 164.501(2) under the definition of “marketing.” If pharmacies or health plans are paying for random patient names and then calling them, the HIPAA Privacy Rule protects against that abusive practice, as well. Under Section 164.501(2), any arrangement in which there is an exchange of either direct or indirect remuneration for health information provided for the purposes of making a communication about an entities’ own product or service would fall under the definition of marketing, and would require an authorization from the individual prior to such a marketing communication. In other words, this provision was specifically developed to avoid abuses of the marketing rules under the Privacy Rule while delicately balancing the need for

quality healthcare, access to healthcare, and a reduction in healthcare costs. HHS addressed the issue in its Final Rule modifications on August 14, 2002 in response to comments:

In further response to comments, the Department has added new language to the definition of “marketing” to close what commenters perceived as a loophole that a covered entity could sell protected health information to another company for the marketing of that company’s products or services. For example, many were concerned that a pharmaceutical company could pay a provider for a list of patients with a particular condition or taking a particular medication and then use that list to market its own drug products directly to those patients. The commenters believed the proposal would permit this to happen under the guise of the pharmaceutical company acting as a business associate of the covered entity for the purpose of recommending an alternative treatment or therapy to the individual. The Department agrees with comments that the potential for manipulating the business associate relationship in this fashion should be expressly prohibited. Therefore, the Department is adding language that would make clear that business associate transactions of this nature are marketing. Marketing is defined expressly to include “an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.” These communications are marketing and can only occur if the covered entity obtains the individual’s authorization pursuant to Sec. 164.508. The Department believes that this provision will make express the fundamental prohibition against covered entities selling lists of patients or enrollees to third parties, or from disclosing protected health information to a third party for the marketing activities of the third party, without the written authorization of the individual.⁴⁰

In other words, a health care entity would not be able to sell its list of patients to another company without written authorization of the individual, whether or not the “arrangement” happens to fit under the definition of a business associate under the Privacy Rule. This direct prohibition, contained in the Privacy Rule definition of “marketing” itself, and the requirement that all marketing be conducted only after authorization is obtained, prevents telemarketing abuses. Indeed, HHS was very concerned with this issue and noted extensively in its Notice of

⁴⁰ 67 Fed. Reg. 53182, 53187 (Aug. 14, 2002).

Final Rule for HIPAA Privacy that this loophole was being closed in response to concerns for individual privacy. In its Notice of Final Rule for HIPAA Privacy, HHS made it clear that this loophole was now being closed in response to the public concern for protecting individuals and their privacy:

The Privacy Rule, both as published in December 2000 and as proposed to be modified in March 2002, has always prohibited covered entities from selling protected health information to a third party for the marketing activities of the third party, without authorization. Nonetheless, in response to continued public concern, the Department has added a new provision to the definition of “marketing” to prevent situations in which a covered entity could take advantage of the business associate relationship to sell protected health information to another entity for that entity’s commercial marketing purposes. The Department intends this prohibition to address the potential financial conflict of interest that would lead a covered entity to disclose protected health information to another entity under the guise of a treatment exemption.⁴¹

Business associates are bound by the same HIPAA Privacy Rules of Covered Entities because they must sign a business associate agreement with Covered Entities that says it is so bound:

(2) Implementation specifications: Business associate contracts. A contract between the covered entity and a business associate must: (i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart ...⁴²

In other words, business associates are bound by the requirements of the HIPAA Privacy Rules through their business associate agreements which they are required to enter into with Covered Entities. Failure to have a proper business associate agreement, with the myriad of requirements specified therein by Section 164.504, will subject the Covered Entity to sanctions, including monetary penalties.

⁴¹ 67 Fed. Reg. at 53188-89 (Aug. 14, 2002).

⁴² 45 CFR § 164.504(e)(2).

Prior to the HITECH Act, the Privacy Rule applied to business associates pursuant to a contractual obligation rather than a regulatory obligation. Subsequent to passage of the HITECH Act, most provisions of the Privacy Rule are directly applicable to business associates, and such business associates may be subjected to civil and criminal penalties for non-compliance.⁴³ Therefore, the HIPAA Privacy Rule would prevent business associates of Covered Entities from engaging in prohibited uses or disclosures of PHI that apply to Covered Entities.

The exception to the HIPAA marketing rules for covered entities and their business associates is restrictive so patients do not receive third party telemarketing calls. The FTC determined health-related automated calls are regulated by HIPAA and the FTC could rely on HIPAA requirements to ensure that confidential health information is kept private.⁴⁴ The FCC should do the same.

2. The HIPAA Minimum Necessary Rule.

The “minimum necessary rule” under the HIPAA Privacy Rule adds yet another layer of protection against abuses of pre-recorded calls. The minimum necessary rule requires generally that health care providers and business associates use and disclose the minimum information necessary to carry out an objective. For example, Covered Entities, and their business associates, are limited in the amount of information that can be disclosed in a particular situation, depending on the circumstance. The Rule does not prohibit covered entities from leaving messages for patients on their answering machines. However, to reasonably safeguard the individual’s privacy, covered entities should take care to limit the amount of information disclosed on the answering machine. For example, a covered entity might want to consider leaving only its name and

⁴³ Pub. L. No. 111-5§ 13404, 123 Stat 115, 264.

⁴⁴ *Telemarketing Sales Rule, Final Rule Amendments*, 73 Fed. Reg. 51164, 51189-92 (Aug. 29, 2008).

number and other information necessary to confirm an appointment, or ask the individual to call back. Healthcare providers and their fiduciaries are limited to providing health information that is directly related to the patient's care or health plan.

A covered entity is also permitted to leave a message with a family member or other person who answers the phone when the patient is not home. The Privacy Rule permits covered entities to disclose limited information to family members, friends, or other persons regarding an individual's care, even when the individual is not present. However, covered entities should use professional judgment to assure that such disclosures are in the best interest of the individual and limit the information disclosed.⁴⁵

Furthermore, an authentication procedure ensures that any PHI that is disclosed is disclosed only to the proper individual. In fact, many entities use one or more levels of authentication before disclosing PHI to a member. The two most widely utilized authentication methods are 1) to ask call recipients to answer whether they are the intended recipient through a yes/no question; and 2) to use a numeric authentication such as the intended recipient's birth date, member ID, etc. Failure to use any type of authentication, or freely disclosing PHI on phone messages would subject entities to penalties under the HIPAA Privacy Rules as a wrongful use and disclosure of PHI.

Because pharmacies and health plans are Covered Entities, they would violate the fundamental restrictions on uses and disclosures of PHI if they randomly call individuals with whom they do not somehow have a treatment or preexisting health care business relationship. In addition, pharmacies will not randomly call patients to get them to switch pharmacies because

⁴⁵ 45 C.F.R. § 164.510(b)(3).

doing so would violate the fundamental requirements of HIPAA Privacy Rules, punishable by the imposition of fines. For example, for a health plan to simply call a random individual, not enrolled in its health plan, such a call to the individual would presumably be a “marketing” call, as defined under the HIPAA Privacy Rule, which would require an authorization from the individual before the call is made. A use or disclosure of PHI for marketing cannot be made without first obtaining an authorization from the individual.

HIPAA permits healthcare organizations to contact consumers for purposes related to their treatment but not for marketing purposes. Healthcare organizations may communicate with beneficiaries about health-related products or services that are provided by or included in a beneficiary’s health plan. HHS explains:

Thus, it would not be marketing for a physician who has developed a new anti-snore device to send a flyer describing it to all of her patients (whether or not each patient has actually sought treatment for snoring). Nor would it be marketing for an ophthalmologist or health plan to send existing patients or members discounts for eye-exams or eye-glasses available only to the patients and members. Similarly, it would not be marketing for an insurance plan to send its members a description of covered benefits, payment schedules, and claims procedures.⁴⁶

During the implementation of healthcare reform, for example, health-related automated calls subject to HIPAA may be used to provide beneficiaries with additional information about their health plans and improve beneficiary access to healthcare.

⁴⁶ U.S. Department of Health & Human Services, Health Information Privacy, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/faq/marketing/281.html>.

B. The FCC’s Prior Consent Rules for Automated Calls Do Not Apply to Health-Related Automated Calls Because Such Calls are Regulated Under HIPAA.

In the *NPRM*, the FCC seeks comment on prior consent requirements for health-related automated calls.⁴⁷ Health-related automated calls are regulated under HIPAA so they are outside the FCC’s automated call prior consent rules. Under HIPAA, only companies with a direct relationship with the consumer or a covered entity are permitted to make health-related automated calls to a consumer.⁴⁸ Because there is a relationship between the consumer and the healthcare provider or its fiduciary, prior written consent is not needed to contact a consumer about health-related issues.⁴⁹ The FTC granted a full exception to its written consent rules for health-related telemarketing calls subject to HIPAA.⁵⁰ The FCC should do the same since HHS determined that the benefits of the calls outweigh any privacy concerns. HIPAA rules prohibit healthcare providers from selling their patient lists for telemarketing purposes and strictly limit the types of calls healthcare providers and their fiduciaries may make to beneficiaries.

Sections 64.1200(a)(1) and (a)(2) of the FCC’s rules require telemarketers to obtain “prior express consent” before delivering autodialed or prerecorded non-emergency messages to a residential or cellular telephone number.⁵¹ Health related calls subject to HIPAA, like debtor calls, are made to a telephone number provided by the consumer in an application. In *ACA*, the FCC determined that calls made to a debtor on a telephone number provided on the debt

⁴⁷ *NPRM*, ¶ 35. If the FCC does not adopt an exemption for health-related automated calls subject to HIPAA, it should adopt an enforcement forbearance policy with respect to such calls. As previously discussed, health-related automated calls are strictly regulated by HIPAA, such calls provide beneficial public health information to consumers, and help reduce healthcare costs for patients and providers.

⁴⁸ 42 U.S.C. §§ 1320 *et seq.*

⁴⁹ *Id.*

⁵⁰ 2008 *Final Rules Amendments*, 73 Fed. Reg. at 51188-92.

⁵¹ 47 C.F.R. §§ 64.1200(a)(1) & (a)(2).

application that are specifically related to the debt, do not violate the FCC's rules.⁵² The calls do not violate the FCC's rules because they are "are made with the 'prior express consent' of the called party" since they are being made to the telephone number provided by the debtor on the debt application.⁵³ In an earlier TCPA order, the Commission concluded that "persons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary."⁵⁴ The House Report to the TCPA, which ultimately became Section 227 of the Act, states: "The restriction on calls to emergency lines, pagers, and the like does not apply when the called party has provided the telephone number of such a line to the caller for use in normal business communications."⁵⁵ Health related calls subject to HIPAA are made to telephone numbers provided by consumers for use in normal business communications. Congress did not intend for the TCPA to restrict calls to residential or cellular telephone numbers provided by a consumer for use in normal business communications. Therefore, the FCC should adopt an express exception to its rules for health-related automated calls subject to HIPAA.

In the *NPRM*, the FCC seeks comment on if it should change its rules to require written consent to receive prerecorded telemarketing messages and if the same requirement should apply to residential and cellular telephones.⁵⁶ Silverlink notes that many consumers use their cellular

⁵² *Rules and regulations Implementing the telephone consumer Protection Act of 1991 and Request of ACA International for Clarification and Declaratory Ruling, Declaratory Ruling*, 23 FCC Rcd 559, ¶¶ 9-11 (2008).

⁵³ *Id.*

⁵⁴ *Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, Report and Order*, 7 FCC Rcd 8752, ¶ 31 (1992) (citing House Report, 102-317, 1st Sess., 102nd Cong. (1991) at 13, "noting that in such instances the called party has in essence requested the contact by providing the caller with their telephone number for use in normal business communications").

⁵⁵ H. Rep. at 17.

⁵⁶ *NPRM*, ¶ 16.

telephones as their residential telephone and if the FCC chooses to adopt written notice requirements, Silverlink supports commenters that advocate for the same notice requirements for residential and cellular telephones.

IV. IT IS IMPORTANT AND IN THE PUBLIC INTEREST FOR THE FCC TO HARMONIZE ITS HEALTH RELATED AUTOMATED CALL RULES WITH THE FTC'S RULES AND HIPAA.

For health-related automated calls subject to HIPAA, the FCC should follow the FTC's lead and create an exception to its telemarketing rules for such calls because such calls are already regulated on the federal level by HHS.

A. Harmonized Health-Related Automated Calls Subject to HIPAA will Help Ensure Consumer Privacy is Protected.

HIPAA includes a detailed regulatory scheme for health-related automated calls that dictate what companies may call consumers and the information that may be contained in those calls. After reviewing the HIPAA privacy and marketing rules, the FTC concluded that health-related automated calls were fully regulated under HIPAA, and that HIPAA carefully balances consumer privacy concerns and consumers' need for public health information.⁵⁷ Accordingly, the FCC should also conclude that health-related automated calls are fully regulated under HIPAA, consumer privacy concerns are fully addressed in HIPAA, and a full exception to the FCC's telemarketing rules for health-related automated calls subject to HIPAA is in the public interest.

Harmonized FTC, FCC and HIPAA health-related call rules will also reduce compliance costs for companies that provide health-related automated calls subject to HIPAA. This will be especially important under the new healthcare reform, as previously discussed, because

⁵⁷ 2008 *Final Rules Amendments*, 73 Fed. Reg. at 51188-92.

healthcare insurance companies will need to reduce costs in order to meet strict MLRs or rebate the cost difference to consumers at the end of the plan year. Healthcare organizations may choose to reduce costs by delivering health information using cost effective, customer-specific health-related automated calls subject to HIPAA. If the FCC adopts an exception to its rules for health-related automated calls subject to HIPAA then companies only need to comply with one set of rules for such calls. The FCC's and FTC's telemarketing rules are complicated, and harmonized rules will make it easier for companies to ensure that they are complying with FCC, FTC and HIPAA rules for health-related automated calls. Companies have limited personnel and financial resources to implement complex laws. The FCC, FTC and HIPAA telemarketing rules are all designed to protect consumer privacy and to prevent consumers from receiving unwanted calls. Since health-related automated calls subject to HIPAA provide important public health information to consumers, harmonized rules will facilitate the continued availability of such calls and protect consumer privacy. If the FCC adopts different rules for health-related automated calls subject to HIPAA, the carefully balanced privacy concerns in HIPAA may be disrupted and companies may discontinue providing health-related information subject to HIPAA to consumers, which would not be in the public interest.⁵⁸

Past experience indicates that the FCC's and FTC's telemarketing rules work best when they are harmonized. For example, Congress directed the FTC and FCC to work together to create and enforce a national Do Not Call list. The agencies entered into an agreement detailing how jurisdiction would be shared and today there is a well functioning Do Not Call list. Experience also indicates that when telemarketing rules differ between the agencies, one agency

⁵⁸ If the FCC determines an exception to its automated call rules for health-related automated calls subject to HIPAA is not in the public interest and prior express consent or written consent is required, Silverlink requests that the FCC forbear enforcing its rules.

may forbear enforcement of its rules or change rules. For example, the FCC adopted an existing business relationship exception to the TCPA. The FTC did not adopt a similar provision. The FTC decided to forebear enforcement because compliance with both sets of rules was not possible because a parallel EBR exception was not adopted. Eventually, the FTC amended its rules to adopt an EBR exception that is similar to the FCC's.

B. If the FCC Does Not Adopt an Exemption for Automated Health-Related Automated Calls Subject to HIPAA, Its Inaction may Cause Confusion.

If the FCC declines to adopt an express exemption from its automated call rules for health-related automated calls subject to HIPAA, such calls will still be permissible because “persons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary.”⁵⁹ Consumers provide a telephone number to a healthcare professional, for example, when subscribing to health insurance, at the time medical services are administered, and when filing prescriptions. Healthcare providers and HIPAA covered entities will still be able to contact their customers in order to provide automated and interactive public health information because of the relationship between the parties and prior express consent was obtained at the time services were provided.⁶⁰

Companies are also required to comply with HIPAA requirements, which further restrict a company's ability to contact consumers and the information that may be provided without first receiving the a consumer's consent. HIPAA provides a detailed regime for how health information may be transmitted to consumers. If the FCC does not adopt an express exemption to

⁵⁹ *1992 TCPA Order*, 7 FC Rcd at 8765, ¶ 31.

⁶⁰ *See ACA*, §§ 9-11 (stating debt related calls made to a telephone number provided by the debtor on the debt application do not violate the FCC's rules).

its automated call rules for health-related automated calls subject to HIPAA, companies and consumers will be faced with two different regulatory regimes for those calls. Under the FCC's rules, the calls are permitted because the telephone number was provided to the healthcare professional by the consumer. However, HIPAA regulates to whom health information may be disclosed and under what circumstances a consumer may be called and by whom. HIPAA rules are stricter than the FCC's rules because of the sensitive nature of health information. FCC inaction may muddy the carefully constructed regulatory regime for health-related automated calls subject to HIPAA that is working and enforced by HHS. An express exemption from the FCC's automated call rules for health-related automated calls subject to HIPAA will ensure that consumer privacy concerns related to health information continue to be regulated by the privacy regime developed in HIPAA.

C. Health-Related Automated Calls Subject to HIPAA Are in the Public Interest.

The TSR and TCPA are designed to prevent nuisance telemarketing calls that invade a consumer's privacy, and to provide guidelines for the FTC and the FCC on how to regulate telemarketing calls. Health-related automated calls subject to HIPAA, unlike telemarketing calls, provide public health information to consumers and are not considered a nuisance. The consumers most in need of the health calls, the sick and the elderly, are unlikely to "opt-in" to receive such messages. The elderly may not take the time to opt-in and the sick may be unable to because they are not well or are unable to complete the opt-in process.

The FCC's approach to automated calls is unnecessary for health-related automated calls subject to HIPAA. Consumers find automated telemarketing calls to be an intrusion into their privacy and a nuisance. Unlike automated telemarketing calls, health-related automated calls

subject to HIPAA provide consumers with health information about prescription renewals, surgery information, changes to healthcare plans and appointment reminders. Other alternative reminders, such as email and letters, are not as effective as telephone reminders. Sending a letter may take too long and does not provide the consumer with the ability to immediately have access to additional information if they have questions. Email is timelier but does not provide the consumer with immediate access to additional information. Both methods require the consumer to take action. A telephone call, however, often allows a consumer access to additional assistance to address their specific questions.

An express exemption to the FCC automated call rules for health-related automated calls subject to HIPAA, will ensure continued consumer access to important health-related information, which is in the public interest. An exemption is also consistent with Congressional mandates that the FCC and the FTC should adopt similar rules since both agencies share jurisdiction over automated calls.

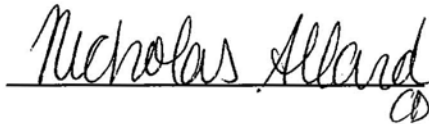
Health-related automated calls are already subject to stringent regulation under HIPAA. The HIPAA regulatory scheme was carefully crafted to protect consumer privacy and to optimize health outcomes. To avoid abuse, HIPAA limits the healthcare organizations that are authorized to deliver automated health-related automated calls to consumers.

V. CONCLUSION

For all of the aforementioned reasons, the FCC should adopt an express exemption from its telemarketing rules for health-related automated calls subject to HIPAA. An express exemption is in the public interest because health-related automated calls are already subject to a

highly regulated regime under HIPAA, the FTC adopted an exemption for health-related automated calls subject to HIPAA, the calls provide important public health information to consumers, the calls are unlike telemarketing calls that are a nuisance to consumers, and the calls are to telephone numbers provided by the beneficiary expressly for receiving health information.

Respectfully submitted,

A handwritten signature in black ink that reads "Nicholas Allard". The signature is written in a cursive style and is positioned above a horizontal line.

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Dated: May 21, 2010

Exhibit A

Automated Call Consumer Survey

□ Methodology and sample summary:

- Using online survey tool Zoomerang, **558 consumers** – unaffiliated with Silverlink - completed a 10 question survey. All respondents currently have health insurance (through an employer, federal health program, or individual policy). The majority of respondents (87%) have received an automated call in the last 12 months. Gender, age, and area of residence were well distributed (complete breakdown available in expanded population section below).

□ Result Highlights:

1. Consumers find health related automated "telemarketing" calls to be far more helpful than typical automated telemarketing calls.	<i>While very few respondents said that they would find an automated call offering a new credit card (2%) or discounted vacation package (5%) helpful, one third thought an immunization or screening reminder would be helpful (31% and 33% respectively), and nearly half (46%) indicated that a refill reminder would be helpful.</i>
2. Consumers are more willing to listen to health related automated calls than to typical automated telemarketing calls.	<i>Similarly, very few respondents indicated that they would be willing to listen to an automated call offering a new credit card (3%) or a vacation package (5%), while at least a third would be willing to listen to health related calls such as refill reminders (43%), screening reminders (34%) and immunization reminders (32%)</i>
3. Although they find health related automated calls helpful, and they are willing to listen to them, most consumers admit they wouldn't go to the trouble of opting in to the calls.	<i>Only 8% of respondents said they would be very likely to sign and send written consent authorizing health related automated calls while 43% said they would be highly unlikely to do so.</i>
4. In general, consumers dislike automated calls....	<i>In response to the question "In general, what is your opinion of automated calls?", 85% of respondents indicated a negative opinion while 13% were neutral and 2% wrote positive responses.</i>
5. ...however those same consumers have a more positive opinion of health related automated calls.	<i>More than half (52%) of the respondents indicated that they had a better opinion of health related automated calls than they did of other types of automated calls.</i>

□ Survey Population information

- 558 respondents (chosen at random among registered Zoomerang panelists – no affiliation with Silverlink)
- All respondents claimed current health insurance coverage (through an employer, Medicare, Medicaid, or privately purchased product)
- **Gender:** 48% (266) female / 52% (292) male
- **Age:**
 - 25-34: 10% (56)
 - 35-44: 18% (102)
 - 45-54: 28% (154)
 - 55-64: 30% (166)
 - 65-74: 11% (64)
 - 75+: 3% (15)
- **Primary Residence (time zone):**
 - Pacific: 16% (89)
 - Mountain: 5% (30)
 - Central: 25% (142)
 - Eastern: 53% (295)

Silverlink Consumer Survey 11/06 (Sample) Results Overview



Date: 11/28/2006 10:16 PM PST
Responses: Completes
Filter: insureds only

In this survey we're going to ask you a few questions about phone calls you might receive from companies in your home. When we say "automated call", we mean a call made to your home in which you interact with a recorded voice rather than a live caller. Thank you for taking time to provide your valuable opinion.

1. Have you received an automated phone call in the past 12 months?

Yes		487	87%
No		57	10%
I don't know		15	3%
Total		559	100%

2. How helpful would you find the following kinds of automated phone calls?






Top number is the count of respondents selecting the option. Bottom % is percent of total respondents selecting the option.	I would not find this call at all helpful	2	3	4	I would find this call very helpful
A call from your financial services company offering a new credit card at a discounted rate.	477 85%	37 7%	30 5%	8 1%	7 1%
A call from your travel company offering a discounted vacation package.	440 79%	51 9%	43 8%	15 3%	10 2%
A call reminding you of a past due payment.	254 45%	49 9%	90 16%	89 16%	77 14%
A call from your pharmacy reminding you to refill a prescription for a medication you take regularly.	162 29%	40 7%	98 18%	104 19%	155 28%
A call from your health plan reminding you to get a routine screening or test recommended by your doctor.	195 35%	60 11%	118 21%	95 17%	91 16%
A call from your health plan reminding you to get an immunization for you or your child.	249 45%	44 8%	92 16%	86 15%	88 16%

3. How would you feel about having the following kinds of automated phone calls delivered to your home?

Top number is the count of respondents selecting the option. Bottom % is percent of total respondents selecting the option.	I would not be willing to listen to this kind of call.	2	3	4	I would be very willing to listen to this kind of call.
A call from your financial services					

company offering a new credit card at a discounted rate.	471 84%	38 7%	30 5%	13 2%	7 1%
A call from your travel company offering a discounted vacation package.	428 77%	58 10%	44 8%	21 4%	8 1%
A call reminding you of a past due payment.	261 47%	58 10%	89 16%	70 13%	81 14%
A call from your pharmacy reminding you to refill a prescription for a medication you take regularly.	163 29%	48 9%	111 20%	98 18%	139 25%
A call from your health plan reminding you to get a routine screening or test recommended by your doctor.	192 34%	63 11%	116 21%	87 16%	101 18%
A call from your health plan reminding you to get an immunization for you or your child.	240 43%	40 7%	97 17%	85 15%	97 17%



4. How likely would you be to sign and send a written consent form authorizing your healthcare company to deliver health related automated calls to your home?

Very unlikely		241	43%
		81	14%
		120	21%
		74	13%
Very likely		43	8%
Total		559	100%

7. Do you currently have health insurance coverage? (including insurance through an employer, Medicare, Medicaid, or privately purchased insurance?)

Yes		559	100%
No		0	0%
I don't know		0	0%
Total		559	100%

8. What is your gender?





Female		267	48%
Male		292	52%
Total		559	100%

9. What is your age?

18 - 24		1	0%
25 - 34		56	10%
35 - 44		103	18%
45 - 54		154	28%
55 - 64		166	30%

65 - 74		64	11%
75+		15	3%
Total		559	100%

10. What time zone is your primary residence in?

Pacific		90	16%
Mountain		30	5%
Central		142	25%
Eastern		295	53%
Alaska		0	0%
Hawaii		2	0%
Other, please specify		0	0%
Total		559	100%

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